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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,644	11/25/2003	Giuseppe Arnaldo Maria Giardina	P31817C3	7108

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EXAMINER

DAVIS, ZINNA NORTHINGTON

ART UNIT PAPER NUMBER

1625

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/721,644	<b>Applicant(s)</b> GIARDINA ET AL.	
	<b>Examiner</b> Zinna Northington Davis	<b>Art Unit</b> 1625	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11,13,14,16,18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11,13,14,16,18 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                             | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11/03</u> . | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

1. Claims 1-11, 13, 14, 16, 18 and 19 are pending. Claims 12, 15, and 17 have been cancelled.
2. Based upon Applicants' remarks filed July 22, 2004, the restriction requirement and election of species request have been withdrawn. The application is examined as a whole.
3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating certain disorders, does not reasonably provide enablement for the prophylaxis of the same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.
5. The recitation of the phrase "treatment or prophylaxis" is broader than the scope of enablement. While the specification provides a method of treating disorders, the specification fails to teach how these compounds are useful in the prophylaxis of all Primary and Secondary Conditions in mammals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following eight different factors (see Ex parte Foreman, 230 USPQ at 547) must be considered in order for the specification to be enabling for what is being

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claimed: the quantity of experimentation necessary the amount of direction or guidance provided, presence or absence of working examples, the nature of invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims.

For the instant application, the specification is not enabling based on at least four of the above mentioned eight factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples and the state of the prior art. The instant compounds are antagonists of tachykinins NK-2 and NK-3 receptors. The compounds have utility in treating disorders where abnormality or high levels of these two tachykinins are implicated. There are no prior art references provided in the specification showing role of tachykinins NK-2 and NK-3 in the etiology of all Primary and Secondary Conditions. There is no guidance in the specification or presence of working examples to show how the instant compounds will have utility in treating disorders drawn to Primary and Secondary Conditions. In the absence of such teachings in the specification and prior art on one hand and absence of guidance or working examples on the other hand, it would require undue experimentation to demonstrate the effectiveness of the instant compounds in treating the conditions at claim 18. Accordingly, the claim and specification are rejected under 35 U.S.C. 112, first paragraph.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 1, 7, 16, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1 and 16 are essential duplicates.

B. Claims 1 and 19 are essential duplicates.

C. Claim 7 improperly depends upon claim 1. See the phrase " moiety of formula (a)".

D. At claim 18, the term "particularly" is subgeneric which is improper.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4, 8-10, 14, 16, 18, and 19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Farina et al (Reference BB).<sup>1</sup>

The instantly claimed compounds are disclosed. At page 2, see the disclosed compound. Additionally, at page 81, Table 6, see example 112, respectively.

10. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

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A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

11. Claims 1-11, 13, 14, 16, 18 and 19 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-21 of copending Application No. 10/474,542. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.


The claims are essential duplicates.

12. The Information Disclosure Statement filed November 25, 2003 has been considered.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682.

14. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

15. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to telephone number is 571-272-1600.

  
**Zinna Northington Davis**  
**Primary Examiner**  
**Art Unit 1625**